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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/226,597	01/07/1999	JULIO PIMENTEL	ANIT0018U-US	9844	
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4813-B EISEN	NHOWER AVENUE		GABEL, GAILENE		
ALEXANDRIA, VA 22304			ART UNIT	PAPER NUMBER	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

general@neifeld.com rneifeld@neifeld.com rhahl@neifeld.com

# Application No. Applicant(s) 09/226,597 PIMENTEL, JULIO Office Action Summary Examiner Art Unit GAILENE R. GABEL 1641 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 16 February 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4.12-19 and 22-24 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-4.12-19 and 22-24 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some \* c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Tirformation Disclosurs Statement(s) (PTO/SE/CC)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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## DETAILED ACTION

### Amendment Entry

 Applicant's amendment and response filed February 16, 2009 is acknowledged and has been entered. Claim 1 has been amended. Claims 5, 24, and 32-35 have been cancelled. Accordingly, claims 1-4, 12-19, and 22-24 are pending and are under examination.

## Rejections Withdrawn

- 2. All rejections not reiterated herein have been withdrawn.
- The rejections of claims 5, 24, and 32-35 are now moot in light of Applicant's cancellation of the claims.

#### New Grounds of Rejection

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 12-19, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is vague and indefinite in reciting, A method of "controlling" because it is unclear what Applicant intends to encompass in the term "controlling" as used in the claim.

Claim 1 is also vague and indefinite in reciting, "effective" because the term effective is a subjective term that lacks a comparative basis for defining its metes and bounds.

Perhaps, Applicant intends, "... comprising: feeding a mammal food containing an amount of a liposome-encapsulated anti-lipase antibody effective to decrease body weight gain per unit of food of said mammal after eating the food; thereby, controlling the weight of the mammal" which is supported in page 3 of the specification.

Claim 4 lacks antecedent basis in reciting, "said animal."

Claim 12 is confusing in reciting, "... antibody is formed prior to said feeding" since the antibody is intended to be fed when combined with the food as recited in claim

 Perhaps, Applicant intends, "... antibody is formed and mixed with the food prior to said feeding"

Claim 13 lacks antecedent basis in reciting, "said animal."

Claim 14 lacks antecedent basis in reciting, "said animal" first and second occurrence.

Claim 15 lacks antecedent basis in reciting, "said animal" first and second occurrence.

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Claim 16 is vague and indefinite in reciting, A composition for "controlling" because it is unclear what Applicant intends to encompass in the term "controlling" as used in the claim.

Claim 16 is also vague and indefinite in reciting, "effective" because the term effective is a subjective term that lacks a comparative basis for defining its metes and bounds.

Perhaps, Applicant intends, "A food composition... comprising: a mixture of food for a mammal and an amount of a liposome-encapsulated anti-lipase antibody effective to decrease body weight gain per unit of food of said mammal after eating the food composition; thereby, controlling the weight of the mammal" which is supported in page 3 of the specification.

Claim 19 is confusing in reciting, "... antibody is in one of a wet state and a freeze dried state." Perhaps, Applicant intends, "... antibody is in a wet state or a freeze dried state."

Claim 23 lacks antecedent basis in reciting, "said animal."

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 12-19, and 22-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-7 of U.S. Patent No. 7,344,713 in view of Cook et al. (US Patent 5,919,451). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions teach and recite a method of reducing weight gain in mammals by feeding them or orally administering to them antilipase antibodies with food in an amount effective to decrease body weight gain by decreasing the activity of lipase in digestive system.

US Patent No. 7,334,713 differs from the instant invention in failing to teach that the antilipase antibodies are liposome encapsulated.

Cook et al. disclose a method of feeding to mammals food composition comprising a liposome-encapsulated antibody (col. 1, line 1 to column 2, line 6). The antibody may be provided in solution in a wet state, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core without a carrier (freeze-dried) such as a powder. The antibody is, however, preferably encapsulated in liposome (col. 2, lines 22-46).

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to encapsulate the anti-lipase antibodies of US Patent 7,344,713 into liposomes as taught by Cook, because anti-lipase antibodies appear to constitute obvious variations of antibodies that are specific for gut antigens that can be liposome encapsulated to protect them from acidity that occurs in digestive system, and Cook specifically taught that any antibody specific for endogenous antigens present in digestive system can be liposome-encapsulated for incorporation with food intake.

# Response to Arguments

- Applicant's arguments with respect to claims 1-4, 12-19, and 22-24 have been considered but are moot in view of the new grounds of rejection.
- No claims are allowed.
- Any inquiry concerning this communication or earlier communications from the
  examiner should be directed to GAILENE R. GABEL whose telephone number is
  (571)272-0820. The examiner can normally be reached on Monday, Tuesday,
  Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/ Primary Examiner, Art Unit 1641

April 24, 2009